

Applicant: Toshio Miyata
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REMARKS

Claims 1-15 were pending prior to this Response. By the present communication, claims 16-38 have been added, claims 1-6, 8, 10-11 and 13-14 have been cancelled without prejudice, and claims 7, 9, 12 and 15 have been amended to define Applicant's invention with greater particularity. The new claim language adds no new matter, being fully supported by the Specification and claims. Upon entry of the present amendment, claims 7, 9, 12, 15 and 16-38 will be pending.

The Objection to the Claims

The Office Action indicates claims 4-13 as presented in the preliminary amendment were misnumbered and have been renumbered as claims 6-15. The Examiner advises that should claims 4 and 5 be found allowable, claims 11 and 13, respectively will be objected to as being substantial duplicates thereof (Office Action, page 2). Claims 4, 5 and 11 have been cancelled by the present amendment, rendering the objection moot as to any substantial duplication in claims. In view of the above amendments, Applicant respectfully requests reconsideration and withdrawal of the objection to claims 5 and 13 as being a substantial duplicates.

The Rejection under 35 U.S.C. § 102(b)

Applicant respectfully traverses the rejection of claims 1-5 and 10-14 under 35 U.S.C. § 102(b) as allegedly being anticipated by Kumar (U.S. Patent No. 6,117,451). As claims 1-5, 10-11 and 13-14 have been cancelled without prejudice, the following remarks are in support of the peritoneal dialysate solution of claim 12. Applicant submits that the invention peritoneal dialysate solutions, as defined by independent claim 12, distinguish over the disclosure of Kumar by requiring "a peritoneal dialysate solution." Applicant's invention is based on the discovery that a biguanide agent is sufficient as an active agent in a therapeutic composition that is useful to treat the condition of carbonyl stress, either in vivo or ex vivo, i.e., for peritoneal dialysis.

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Prior to Applicant's invention, those of skill in the art had believed that biguanide agents "lack the glycation-suppressing activity" (Specification, ¶ [0010]).

Kumar fails to describe any peritoneal dialysate solution. Instead, Kumar discloses a composition for in vivo use that comprises metformin and various "excipients." In the pharmaceutical industry, the term "excipient" denotes the pharmaceutically inactive matrix material used to guarantee good tablet formation or integrity. This is the very sense in which Kumar uses the term excipient. By contrast, Kumar is absolutely silent regarding a "solution" comprising metformin as useful for any purpose.

To prove anticipation it must be shown that a single reference discloses each and every element of the claims at issue. Since Kumar discloses "excipients" but is absolutely silent regarding a "solution" comprising metformin hydrochloride for any therapeutic purpose, Applicant respectfully submits that Kumar fails to anticipate the subject matter of amended claim 12 under 35 U.S.C. § 102(b). Accordingly, reconsideration and withdrawal of the rejection over Kumar are respectfully requested.

The Rejection under 35 U.S.C. § 102(e)

Applicant respectfully traverses the rejection of claims 1-6, 8 and 10-14 under 35 U.S.C. § 102(b) as allegedly being anticipated by Gatlin (U.S. Patent No. 6,559,188). As claims 1-5 10-11 and 13-14 have been cancelled without prejudice, the following remarks are in support of the peritoneal dialysate solution of claim 12. Applicant submits that the invention peritoneal dialysate solutions, as defined by independent claim 12, distinguish over the disclosure of Gatlin by requiring "a peritoneal dialysate solution." Applicant's invention is based on the discovery that a biguanide agent is sufficient as an active agent in a therapeutic composition that is useful to treat the condition of carbonyl stress, either in vivo or ex vivo, i.e., for peritoneal dialysis. Like Kumar, Gaitlin fails to describe any peritoneal dialysate solution.

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By contrast with Applicant's invention, Gaitlin discloses a composition requiring two active ingredients: nateglinide or repaglinide *and* metformin. Gaitlin fails to disclose that a therapeutic composition which omits nateglinide or repaglinide as active agents is useful for any purpose. In other words, Gaitlin fails to disclose Applicant's discovery that a biguanide agent is sufficient as an active agent in a therapeutic composition, let alone in solution as a peritoneal dialysate composition.

Since Gaitlin fails to disclose each and every element of the invention of independent claim 12, as would be required to establish anticipation under 35 U.S.C. § 102(e), Applicant respectfully requests reconsideration and withdrawal of the rejection over Gaitlin.

Allowable Subject Matter

The Examiner indicates that claims 7, 9 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all subject matter of the intervening claims. Claims 7, 9 and 15 have been rewritten in independent form including all subject matter of any intervening claims. Therefore, Applicant respectfully submits, based upon the amendments and the above remarks that all claims 7, 9 and 15, and all claim dependent thereon, are now in condition for allowance. Accordingly, reconsideration and withdrawal of the objection to claims 7, 9 and 15 are respectfully requested.

In summary, for the reasons set forth herein, Applicant maintains that claims 7, 9, 12, and 16-38 clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending.

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If the Examiner would like to discuss any of the issues raised in the Office Action,
Applicant's representative can be reached at (858) 677-1456.

Respectfully submitted,

Dated: January 14, 2004



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Enclosures: Petition for Extension of Time (1 month)